ACR Full-Field Digital Mammography Accreditation - 2002 Update

Last Year at This Time

- The Full-Field Digital Accreditation (FFDM) Module was complete and was mid-way through ACR leadership approval
- We had hoped for final ACR approval by end of Sept 2001
- Module was manufacturer-specific (first GE)
  - Exposure control mechanisms are different
  - Due to FDA regs, required QC is different

Since Then

- In early October, ACR sent the FFDM Module documents to the Executive Committee of the ACR's Board of Chancellors and the FDA for review
- In Mid-October, FFDM Module approved by the Executive Committee of the ACR's Board of Chancellors
- In mid November, FDA instructed ACR to submit a formal application for approval of the FFDM Accreditation Module (to include the same requirements addresses as part of ACR accreditation body application approved by the FDA on December 20, 2000.)

Formal Application Submission

- At the beginning of July 2002, ACR submitted a complete formal FFDM Accreditation Module application to FDA
- At the end of July, after initial review of the application, FDA advised ACR that the information provided with the alternative standard request was insufficient
- In early August, the digital subcommittee collected additional data to supplement the alternative standard request
- The revision to the alternative standard request is currently under internal review prior to re-submission to FDA

Proposed Accreditation Process for Full-Field Digital Mammography

General Process Will Not Differ

- Paperwork will depend on time left on facility's certification and accreditation
  - <13 months – all units must go through early renewal at usual fee
  - >13 months – the FFDM unit must complete "mid-cycle" accreditation at a reduced fee
- Facilities will be able to have "stand-alone" digital systems (no screen-film required)

Clinical Image Quality Evaluation Will Not Differ

- Images must be submitted on hard copy
- Eight attributes evaluated the same as screen-film
  - Positioning
  - Compression
  - Exposure
  - Contrast
  - Sharpness
  - Noise
  - Artifacts
  - Labeling
- ACR reviewers are qualified in digital under MQSA

Phantom Image Quality Evaluation Will Not Differ

- Images must be submitted on hard copy
- Scoring is the same as screen-film
  - Fibers
  - Specks
  - Masses
  - Subtraction for artifacts
- ACR reviewers are qualified in digital under MQSA

Quality Control Tests — Other Modalities

900.12(e)(6)

“For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.”

Phantom Exposure and Dosimetry

- Exposure control mechanism is different for each manufacturer's FFDM system
  - Facility instructions must be unit-specific
  - e.g., GE exposure control is impacted by the thickest/densest part of the breast
  - Accreditation phantom rim and TLD holder result in higher exposure than 4.2 cm breast
- Revised instructions for GE
  - Expose 4.2 cm tissue eq acrylic block under AEC to determine appropriate technique
  - Then expose accreditation phantom and dosimeter with manual technique

Technologist Tests (GE)

1. Monitor Cleaning
2. Viewing Conditions for the Review Work Station (RWS)
3. Darkroom Cleanliness (if app)
4. Processor QC (if app)
5. Mobile Unit Quality Control (if app)
6. Flat Field
7. Image Quality (Phantom)
8. Viewbox and Viewing Conditions
9. MTF Measurement
10. AOP Mode and Signal-to-Noise (SNR)
11. Visual Checklist
12. Monitor Calibration
13. Repeat Analysis
14. Analysis of Fixer Retention (if app)
15. Compression Force (Pressure)
16. Darkroom Fog (if app)
17. Laser Film Printer QC

Medical Physicist Tests (GE)

1. Collimation
2. Focal Spot Performance
3. Entrance Exp, Ave Glandular Dose & Repro
4. Artifact Eval & Flat Field Uniformity
5. Viewing Condition Check and Setting
6. Monitor Calibration (Brightness/Contrast)
7. Image Quality – SMPTE Pattern
8. RWS Screen Uniformity (required for “Eq Eval” and as necessary)
9. kVp Accuracy & Repro
10. Beam Quality (HVL)
11. Radiation Output
12. Mammo Unit Assembly Evaluation
13. Flat Field (see rad tech tests)
14. Image Quality (Phantom) (see rad tech tests)
15. MTF Measurement (see rad tech tests)
16. AOP Mode and Signal-to-Noise (SNR) (see rad tech tests)

FFDM Accreditation for Other Units

- After final FDA approval of the first module, ACR will complete development of modules for other FDA-approved units